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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

Complete if Known

Application Number	09/923,791
Filing Date	August 8, 2001
First Named Inventor	David Hung
Group Art Unit	1645-1648
Examiner Name	FBA U. Winkler
Attorney Docket Number	05284.00130

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

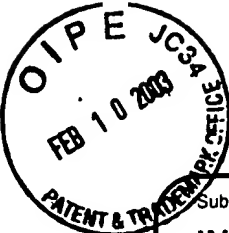
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
W	9	M. WIDSCHWENDTER et al., "Methylation and silencing of the retinoic acid receptor-beta2 gene in breast cancer", J. National Cancer Institute, 5-17-00; 92(10), pp. 826-832, Abstract Only
	10	K.E. CONWAY et al., "TMS1, a novel proapoptotic caspase recruitment domain protein, is a target of methylation-induced gene silencing in human breast cancers", Cancer Research, 11-15-00; 60(22), pp. 6236-6242, Abstract Only
	11	K.M. LAU, "Expresion of estrogen receptor (ER)-alpha and ER-beta in normal and malignant prostatic epithelial cells: regulation by methylation and involvement in growth regulation", Cancer Research, 6-15-00, 60(12), pp. 3175-3182, Abstract Only
	12	A. VILAIN et al., "DNA methylation and chromosome instability in breast cancer cell lines", FEBS Lett, 10-29-99, 460(2), pp. 231-234, Abstract Only
	13	S.M. SIRCHIA et al., "Evidence of epigenetic changes affecting the chromatin state of the retinoic acid receptor beta2 promoter in breast cancer cells", Oncogene, 3-16-00, 19(12), pp. 1556-1563, Abstract Only
	14	S. MILUTINOVIC et al., "DNA methyltransferase inhibition induces the transcription of the tumor suppressor p21(WAF1/CIP1/sdi1)", J. Biological Chem., 3-3-00, 275(9), pp. 6353-6359, Abstract Only
	15	P.M. WARNECKE et al., "Cytosine methylation and human cancer", Curr. Opin. Oncol, 1-00, 12(1), pp. 68-73, Abstract Only
	16	J. SONG et al., "Chemopreventive effects of dietary folate on intestinal polyps in Apc+/-Msh2-/- mice", Cancer Research, 6-15-00, 60(12), pp. 3191-3199, Abstract Only
	17	Y. NIWA et al., "BRCA1 Expression Status in Relation to DNA Methylation of the BRCA1 Promoter Region in Sporadic Breast Cancers," Jpn J. Cancer Research, 5-00, 91(5), pp. 519-526, Abstract Only
	18	R.G. LAPIDUS et al., "The loss of estrogen and progesterone receptor gene expression in human breast cancer", J. Mammary Gland Biol. Neoplasia, 1-98, 3(1), pp. 85-94, Abstract Only

Examiner Signature	<i>U. Winkler</i>	Date Considered	4/9/03
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Attorney Docket Number	05284.00130

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Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
HW	o	G.J. HAMMONS, "Increased expression of hepatic DNA methyltransferase in smokers", Cell Biol Toxicol, 1999; 15(6), pp. 389-394, Abstract Only	
	o	F.E. DOMANN et al., "Epigenetic silencing of maspin gene expression in human breast cancers", Int. J. Cancer, 3-15-00; 85(6), pp. 805-810, Abstract Only	
	o	B.K. NAYAK et al., "Mutation and methylation status of p53 gene promoter in human breast tumours", Tumour Biol, 11-12/1999, 20(6), pp. 341-346, Abstract Only	
	o	Y.I. KIM, "Folate and cancer prevention: a new medical application of folate beyond hyperhomocysteinemia and neural tube defects", Nutr. Rev., 10-99, 57(10), pp. 314-321, Abstract Only	
	o	S.J. NASS et al., "Expression of DNA methyl-transferase (DMT) and the cell cycle in hman breast cancer cells", Oncogene, 12-9-99, 18(52), pp. 7453-7461, Abstract Only	
	o	M. ESTELLER, "Epigenetic lesions causing genetic lesions in human cancer. promoter hypermethylation of DNA repair genes", Eur J Cancer, 12-00, 36(18), pp. 2294-2300, Abstract Only	
	o	S.S. DEHAL et al., "The aromatase inactivator 4-hydroxyandrostenedione (4-OH-A) inhibits tamoxifen metabolism by rat hepatic cytochrome P-450 3A: potential for drug-drug interaction of tamoxifen and 4-OH-A in combined anti-breast cancer therapy", Drug Metab Dispos, 3-99, 27(3), pp. 389-394, Abstract Only	

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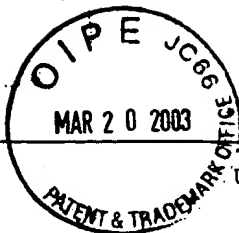
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Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No.		Appln. No. 09/923,791	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicant David Hung		Group 164	
				Filing Date August 8, 2001			
U.S. PATENT DOCUMENTS							
*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
W		6,221,622	04/24/01	Love	-	-	
W		6,413,228	07/02/02	Hung et al.	-	-	
FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation Yes No
W	9	0 502 485 B1	10/23/96	European Patent Office	-	-	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
W	-	Leborgne, Intraductal Biopsy of Certain Pathologic Processes of the Breast, Surgery 19:47-54 (1946)					
		Papanicolaou et al., Exfoliative Cytology of the Human Mammary Gland and Its Value in the Diagnosis of Cancer and Other Diseases of the Breast, Cancer 11:377-409 (1958)					
	o	Buehring, Screening for Breast Atypias Using Exfoliative Cytology, Cancer 43(5):1788-1799 (1979)					
	o	Makita et al., Duct Endoscopy and Endoscopic Biopsy in the Evaluation of Nipple Discharge, Breast Cancer Research and Treatment 18:179-188 (1991)					
	-	Jin et al., Study of Tumor Markers in Mammary Ductal Lavage for Early Detection of Breast Carcinoma, Zhongguo Zhong Liu Lin Chuang 23(6):381-385 (1996), with English translation					
	o	Love et al., Breast-Duct Endoscopy to Study Stages of Cancerous Breast Disease, Lancet 348:997-999 (1996)					
A	-	Sauter et al., Nipple Aspirate Fluid: A Promising Non-Invasive Method to Identify Cellular Markers of Breast Cancer Risk, British J. Cancer 76(4):494-501 (1997)					
Examiner	John W. [Signature]			Date Considered 4/9/03			
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Attorney Docket Number	005284.000130

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	o	Goodson WH & King EB, Chapter 4: Discharges and Secretions of the Nipple, The Breast Comprehensive Management of Benign and Malignant Diseases, 2 nd Ed, Vol. 2, Bland & Kirby eds. W.B. Saunders Co., Philadelphia, PA, pp 51-74, 1998	
	o	Wrensch et al, Breast Cancer Incidence in Women with Abnormal Cytology in Nipple Aspirates of Breast Fluid, American journal of Epidemiology, Vol. 135, No. 2, pp 130-141, 1992	
	o	Sauter et al, Nipple aspirate fluid: a promising non-invasive method to identify cellular markers of breast cancer risk, British Journal of Cancer, Vol. 76(4), pp 494-501, 1997	
	o	Petrakis, Studies on the Epidemiology and Natural History of Benign Breast Disease and Breast Cancer Using Nipple Aspirate Fluid, Cancer Epidemiology, Biomarkers & Prevention, Vol. 2, pp 3-10, 1993	
	o	Petrakis, Physiologic, biochemical and cytologic aspects of nipple aspirate fluid, Breast Cancer Research and Treatment, Vol. 8, pp 7-19, 1986	
	o	Wrensch et al, Factors associated with obtaining nipple aspirate fluid: Analysis of 1428 women and literature review, Breast Cancer Res. Treat, Vol. 15, pp 39-21, 1990	
	o	Wrensch, Breast Fluid Cholesterol and Cholesterol B-Epoide Concentrations in Women with Benign Breast Disease, Cancer Res., Vol. 49, pp 2168-2174, 1989	
		King et al, Nipple Aspirate Cytology for the Study of Breast Cancer Precursors, J. Natl Cancer Inst, Vol. 71, pp 1115-21, 1983	
	?	Papanicolaou et al, Exfoliative Cytology of the Human Mammary Gland and Its Value in the Diagnosis of Cancer and Other Diseases of the Breast, Cancer, Vol. 11, pp 377-409, 1958	
	o	Sartorius et al, Cytologic Evaluation of Breast Fluid in the Detection of Breast Disease, J. Natl Cancer Inst, Vol. 59, pp 1073-1080, 1977	
		Fryberg and Masood Copeland EM 3d, Bland KI, (Ductal carcinoma in situ of the breast) Surgery, Gynecology & Obstetrics, Vol. 177(4), pp 425-40, 1993	

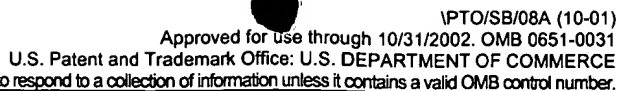
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Application Number	09/923,791
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First Named Inventor	David Hung
Group Art Unit	1645
Examiner Name	Unknown
Attorney Docket Number	005284.00130

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ^e
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